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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,689	08/05/2003	Yong Moon Choi	098390-34217A	7580
26345	7590	06/03/2004	EXAMINER	
GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE 1 RIVERFRONT PLAZA NEWARK, NJ 07102-5497			CHANNAVAJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/634,689	Applicant(s) CHOI ET AL.	
	Examiner Lakshmi S Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8-5-03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

IDS dated 8-5-03 is acknowledged.

Claims 1-8 are presented for examination.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-10 of U.S. Patent No. 6,627,211. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims a method of administering an anticonvulsive agent to the nasal membranes of a mammal and employs the same composition as that claimed in the instant application i.e., an anticonvulsive agent, an aqueous vehicle comprising 30-60% aliphatic alcohol, 30-60% glycol, a surfactant selected from bile salts and lecithin. Accordingly, instant composition is anticipated by the patented claims.

Claim Rejections - 35 USC § 103

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,428,006 to Bechgaard et al (Bechgaard).

Instant claim 1 is directed to a pharmaceutical composition comprising an anticonvulsive agent and an aqueous vehicle containing 30-60% aliphatic alcohol, 30-60% glycol and 0.1-5% bile salt or lecithin; and about 10% by volume of water. Dependent claims recite various amounts of the carrier components or specific anti-convulsive agents.

Bechgaard teaches nasal administration of active substances for rapid absorption of the substance into the blood stream, without causing unacceptable damage to the mucosal membrane. The composition of Bechgaard comprises active substances including anti-epileptic or anti-spasmodic agents such as clonazepam, diazepam etc (col. 4, lines 38-40). Bechgaard recognizes alcohol, glycol and glycol ether as well known carriers for nasal administration of hypnotics (col. 3, lines 26-32) and teaches a carrier or vehicle for the active agent, which comprises n-glycofurol and n-ethylene glycol containing 1-14 ethylene units (col.3, lines 52-67 and col.4, lines 1-9).

Bechgaard does not specifically teach the claimed proportions of aliphatic alcohol, glycol, water and bile salts or lecithin. However, Beechgaard teaches that the composition preferably comprises polyethylene glycol having a molecular weight between 200 and 750 and (col. 7, lines 40-60). Further, Bechgaard suggests incorporating one or more of surfactants and absorption promoters, such as bile salts or their derivatives, lecithin & lysolecithin; solvents, such as alcohol and other excipients in the formulation. Bechgaard also fails to teach the specific anticonvulsive agent of claim 3. However, Bechgaard addresses the same problem of achieving a

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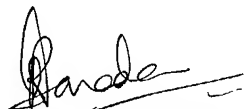
rapid onset and a high plasma level of the medicament as that of the instant invention, and in particular for nasal administration of highly lipophilic substances such as benzodiazepines, in a total volume for as low as 1μ . Accordingly, it would have been obvious for a skilled artisan at the time of the instant invention to add alcohols and surfactants (bile salts or lecithin), to the carrier vehicle of Bechgaard containing glycols, for nasal administration of anticonvulsive substances, because Bechgaard suggests that the alcohols increase solubility and surfactants enhance the absorption of these highly lipophilic substances and thus result in a controlled release formulations with a rapid onset of high plasma concentrations. Further, optimizing the amounts of the carriers such as water, alcohol and glycol, with an expectation to achieve the desired absorption of the drug is within the scope of a skilled artisan. Although Bechgaard does not teach anticonvulsive agent of claim 4, Bechgaard teaches in general anti-epileptic and anti-spasmodic agents are suitable for nasal administration in their method. Accordingly, a skilled artisan would have been able to employ any anticonvulsive agent and yet achieved the same rapid onset of high plasma concentrations as taught by Bechgaard.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615

June 1, 2004